JUL 22 2009

510(k) Summary

CONQUEST® Spinal System

Submitted By:

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510(k) Contact:

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Date Prepared: March 20, 2009

Trade Name: CONQUEST® Spinal System

Common Name: Appliance, Fixation, Spinal Interlaminal

Device Product Code And Classification:

MNH, 888.3070, Class II, Spondylolisthesis Spinal Fixation Device System
MNI, 888.3070, Class II, Pedicle Screw Spinal System
NKB, 888.3070, Class III, Pedicle Screw Spinal System, For Degenerative Disc Disease
KWP, 888.3050, Class II, Spinal Interlaminal Fixation Orthosis

Predicate Devices: **CONQUEST Spinal System (K080767)**
EBI Array Spinal System (K062685)

Device Description:
The CONQUEST Spinal System is a titanium alloy multiple component system comprised of a variety of non-sterile, single use implantable components. When assembled, the components create a rigid structure providing stabilization and promote spinal fusion. The system consists of an assortment of rods, screws, hooks, cross connectors and locking caps.

Intended Use of the Device:

Internal fixation implants are load-sharing devices intended to stabilize and maintain alignment until normal healing occurs. Implants are not intended to replace normal body structures or bear the weight of the body in the presence of incomplete bone healing.

The CONQUEST Spinal System, when properly used, is intended for posterior pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients. It provides stabilization and immobilization of spinal segments as an adjunct to fusion.

When used as a posterior spine thoracic/lumbar system, the CONQUEST Spinal System is indicated for one or more of the following: (1) degenerative disc disease (is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), (2) trauma (i.e. fracture or dislocation), (3) curvatures (scoliosis, kyphosis, and/or lordosis), (4) spinal tumor, (5) failed previous fusion (6) pseudarthrosis, (7) spinal stenosis, (8) spondylolisthesis.

Material:
Manufactured from medical grade titanium alloy described by ASTM F136 (Ti 6AL-4V-ELI) implant grade titanium alloy.

Performance Data:
Biomechanical testing in accordance with ASTM F1717 was conducted to demonstrate substantial equivalence.

Substantial Equivalence:
The CONQUEST® Spinal System was shown to be substantially equivalent to previously cleared devices in indications for use, design, function, and materials used.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 22 2009

Life Spine, Inc.
c/o Mr. Murali Audipudy
RA/QA Manager
2401 W. Hassell Road, Suite 1535
Hoffmann Estates, IL 60169

Re: K090320
Trade/Device Name: CONQUEST® Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWP
Dated: June 19, 2009
Received: June 22, 2009

Dear Mr. Murali,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) number (if known): K090320

Device Name: CONQUEST® Spinal System

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Prescription Use _x_ (Part 21 CFR 801 Subpart D)	And/Or	Over-the-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(EXT for MKM)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090320